

Resources and Housing Branch,  
Attention: Christopher Martin, New  
Executive Office Building, Room 10235,  
Washington, DC 20503.

Dated: March 24, 2005.

**John P. Burke, III,**

*CMS Paperwork Reduction Act Reports  
Clearance Officer, Office of Strategic  
Operations and Regulatory Affairs,  
Regulations Development Group.*

[FR Doc. 05-6534 Filed 4-1-05; 8:45 am]

BILLING CODE 4120-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005D-0112]

#### **Draft Guidance for Industry on Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics; Availability**

**AGENCY:** Food and Drug Administration,  
HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug  
Administration (FDA) is announcing the  
availability of a draft guidance for  
industry entitled "Clinical Trial  
Endpoints for the Approval of Cancer  
Drugs and Biologics."

This is the first of a series of  
guidances that will provide  
recommendations to sponsors on  
endpoints for cancer clinical trials  
submitted to FDA to support  
effectiveness claims in new drug  
applications (NDAs), biologics license  
applications (BLAs), or supplemental  
applications. Sponsors are encouraged  
to use this draft guidance to design  
cancer clinical trials and to discuss  
protocols with the agency. This draft  
guidance provides background  
information and discusses general  
regulatory principles. Each subsequent  
guidance will focus on endpoints for  
specific cancer types (e.g., lung cancer,  
colon cancer) to support drug approval  
or labeling claims. These guidances are  
expected to speed the development and  
improve the quality of protocols  
submitted to the agency to support  
anticancer effectiveness claims.

**DATES:** Submit written or electronic  
comments on the draft guidance by June  
3, 2005. General comments on agency  
guidance documents are welcome at any  
time.

**ADDRESSES:** Submit written requests for  
single copies of the draft guidance to the  
Division of Drug Information (HFD-  
240), Center for Drug Evaluation and  
Research, Food and Drug

Administration, 5600 Fishers Lane,  
Rockville, MD 20857, or the Office of  
Communication, Training, and  
Manufacturers Assistance (HFM-40),  
Center for Biologics Evaluation and  
Research, Food and Drug  
Administration, 1401 Rockville Pike,  
Rockville, MD 20852-1448. Send one  
self-addressed adhesive label to assist  
that office in processing your requests.  
The draft guidance may also be obtained  
by mail by calling the Center for  
Biologics Evaluation and Research  
Voice Information System at 1-800-  
835-4709 or 301-827-1800. Submit  
written comments on the draft guidance  
to the Division of Dockets Management  
(HFA-305), Food and Drug  
Administration, 5630 Fishers Lane, rm.  
1061, Rockville, MD 20852. Submit  
electronic comments to [http://  
www.fda.gov/dockets/ecomments](http://www.fda.gov/dockets/ecomments). See  
the **SUPPLEMENTARY INFORMATION** section  
for electronic access to the draft  
guidance document.

#### **FOR FURTHER INFORMATION CONTACT:**

Grant Williams, Center for Drug  
Evaluation and Research (HFD-  
150), Food and Drug  
Administration, 1451 Rockville  
Pike, Rockville, MD 20852, 301-  
594-5758;

Patricia Keegan, Center for Drug  
Evaluation and Research (HFD-  
107), Food and Drug  
Administration, 1451 Rockville  
Pike, Rockville, MD 20852, 301-  
827-5097; or

Steven Hirschfeld, Center for  
Biologics Evaluation and Research  
(HFM-755), Food and Drug  
Administration, 1401 Rockville  
Pike, Rockville, MD 20852, 301-  
827-6536.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of  
a draft guidance for industry entitled  
"Clinical Trial Endpoints for the  
Approval of Cancer Drugs and  
Biologics." FDA is developing guidance  
on oncology endpoints through a  
process that includes public workshops  
of oncology experts and discussions  
before FDA's Oncologic Drugs Advisory  
Committee. This draft guidance is the  
first in a planned series of cancer  
endpoint guidances. It provides  
background information and general  
principles. The endpoints discussed in  
this draft guidance are for drugs to treat  
patients with an existing cancer. This  
draft guidance does not address  
endpoints for drugs to prevent or  
decrease the incidence of cancer.

This draft guidance is being issued  
consistent with FDA's good guidance

practices regulation (21 CFR 10.115).  
The draft guidance, when finalized, will  
represent the agency's current thinking  
on clinical trial endpoints for the  
approval of cancer drugs and biologics.  
It does not create or confer any rights for  
or on any person and does not operate  
to bind FDA or the public. An  
alternative approach may be used if  
such approach satisfies the  
requirements of the applicable statutes  
and regulations.

##### **II. Comments**

Interested persons may submit to the  
Division of Dockets Management (see  
**ADDRESSES**) written or electronic  
comments on the draft guidance. Submit  
one copy of electronic comments or two  
paper copies of any mailed comments,  
except that individuals may submit one  
paper copy. Comments are to be  
identified with the docket number  
found in brackets in the heading of this  
document. The draft guidance and  
received comments are available for  
public examination in the Division of  
Dockets Management between 9 a.m.  
and 4 p.m., Monday through Friday.

##### **III. Electronic Access**

Persons with access to the Internet  
may obtain the document at [http://  
www.fda.gov/cder/guidance/index.htm](http://www.fda.gov/cder/guidance/index.htm),  
[http://www.fda.gov/cber/  
guidelines.htm](http://www.fda.gov/cber/guidelines.htm), or [http://www.fda.gov/  
ohrms/dockets/default.htm](http://www.fda.gov/ohrms/dockets/default.htm).

Dated: March 26, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05-6647 Filed 4-1-05; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Proposed Data Collection; Comment Request; Survey of Colorectal Cancer Screening Policies, Programs, and Systems in U.S. Health Plans**

**SUMMARY:** In compliance with the  
provisions of section 3507(1)(D) of the  
Paperwork Reduction Act of 1995, for  
opportunity for public comments on  
proposed data collection projects, the  
National Institutes of Health (NIH),  
National Cancer Institute (NCI) has  
submitted to the Office of Management  
and Budget (OMB) a request to review  
and approve the information collection  
listed below. This proposed information  
collection was previously published in  
the **Federal Register** on October 29,  
2004 (Volume 69, No. 209, pages 63159-  
63160) and allowed 60 days for public